

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 05 DEC 2005

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Applicant's or agent's file reference P200400341WA	FOR FURTHER ACTION		See Form PCT/IPEA/416																
International application No. PCT/DK2005/000189	International filing date (day/month/year) 21.03.2005	Priority date (day/month/year) 26.03.2004																	
International Patent Classification (IPC) or national classification and IPC A61M5/158																			
Applicant UNOMEDICAL A/S et al.																			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> <i>sent to the applicant and to the International Bureau</i> a total of sheets, as follows:</p> <ul style="list-style-type: none"> <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. <p>b. <input type="checkbox"/> <i>(sent to the International Bureau only)</i> a total of (indicate type and number of electronic carrier(s)), containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																			
<p>4. This report contains indications relating to the following items:</p> <table> <tbody> <tr> <td><input checked="" type="checkbox"/> Box No. I</td> <td>Basis of the opinion</td> </tr> <tr> <td><input type="checkbox"/> Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/> Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/> Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/> Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/> Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </tbody> </table>				<input checked="" type="checkbox"/> Box No. I	Basis of the opinion	<input type="checkbox"/> Box No. II	Priority	<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/> Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/> Box No. VI	Certain documents cited	<input type="checkbox"/> Box No. VII	Certain defects in the international application	<input checked="" type="checkbox"/> Box No. VIII	Certain observations on the international application
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Date of submission of the demand 08.10.2005	Date of completion of this report 02.12.2005																		
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Krassow, H Telephone No. +49 89 2399-2096																		
 																			

**INTERNATIONAL PRELIMINARY REPORT
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3 and 23.1(b))
 - publication of the international application (under Rule 12.4)
 - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-19 as originally filed

Claims, Numbers

1-21 as originally filed

Drawings, Sheets

1/27-27/27 as originally filed

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. The amendments have resulted in the cancellation of:
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):

4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-21
	No: Claims	
Inventive step (IS)	Yes: Claims	1-21
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

D2: US-A-5 522 803 (TEISSEN-SIMONY CLAUDE) 4 June 1996 (1996-06-04)

1. **Under the explicit provision that claim 1 had been clarified in the respect as detailed under Re Item VIII below**, the subject-matter of claim 1 would have fulfil the requirements of the PCT.

The most relevant prior art is disclosed in D2 and comprises an infusion set according to the preamble of claim 1 from which conventional set that of claim 1 would differ in retention devices (4) which are extending from the upper surface of the main surface of the base part (2) and in that the arms comprise means (10) corresponding to the retention devices (4) and suitable for disengagement of the arms from the retention devices by moving the arms laterally inwards and also by moving them laterally outwards, as well as, by moving them upwards away from the base part.

Thus, the connector (0A) can still easily be disconnected from the infusion part (0B) when movement of an arm towards the inward direction, which is normally necessary in the case of a conventional snap fastening mechanism like that shown in D2, is obstructed as the arm can simply be moved into one of the other directions for disengagement.

2. The dependent claims 2-21 define additional features of preferred embodiments of the infusion set according to claim 1. Therefore, their subject-matter would also fulfil the requirements of the PCT.

Re Item VIII

Certain observations on the international application

1. The subject-matter of **claim 1 is unclear** (Article 6 PCT).

It is not apparent from the wording of claim 1 that the at least two arms (9) should be disengageable from the retention devices (4) **also by moving them laterally outwards and moving them upwards away from the base part as argued by the applicant before the IPEA**. This functional feature, which is at least implicitly clear and obvious

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(SEPARATE SHEET)**

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from all the figures, should have been explicitly defined in claim 1 in order to sufficiently distinguish its subject-matter from the otherwise novelty destroying disclosure of D2.